DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

January 30, 2001

WARNING LETTER
CHI-13-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William A. Pietra, President
American Health Service
a.k.a. MED-VET International
14092 Lambs Lane
Libertyville, IL 60048

Dear Mr. Pietra:

During the inspection of your firm from May 22 to June 21, 2000, Investigator Chad Schmear determined your firm distributes syringes, sutures, intravenous catheters, biopsy needles, and spinal needles. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your firm's sutures for human use are misbranded within the meaning of Section 502(f)(1) of the Act, in that the labeling for this device fails to bear adequate directions for use for the purposes for which it is intended, because adequate directions cannot be written for sutures that have expired, and are labeled as sterile.

According to Section 201(m) of the Act, the term "labeling" means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Your syringes, intravenous catheters, biopsy needles, and spinal needles are misbranded within the meaning of Section 502(q)(2) of the Act, in that they were sold and distributed in violation of Section 520(e) of the Act, which requires that syringes, intravenous catheters, biopsy needles, and spinal needles be restricted to sale, distribution, or use only upon the written or oral authorization of a practitoner licensed by law to use the device.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine that your systems caused the problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office, in writing, within 30 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 30 working days, state the reason for the delay and the time within which the corrections will be completed. Your response should be sent to Michael Lang, Compliance Officer.

You may obtain general information about all of FDA's requirements for manufacturers and distributors of medical devices by contacting our Division of Small Manufacturer's Assistance at 800-638-2041 or through the Internet at http://www.fda.gov.

If you have any questions regarding this letter, please contact Mr. Lang at (312) 353-5863 x171.

Sincerely,

\s\
Raymond V. Mlecko
District Director